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10/650,521	08/28/2003	Edgar Hommann	33332/US	6807

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David E. Bruhn  
DORSEY & WHITNEY LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/650,521

Applicant(s)

HOMMANN ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

The objection to the specification has been withdrawn in light of the amendment to claim 12 in the response filed 5/16/05.

### ***Drawings***

The objection to the drawings are withdrawn in light of the amendment to claim 12 in the response filed 5/16/05.

### ***Claim Objections***

The previous objection to claim 1 is withdrawn in light of the amendment to claim 1 in the response filed 5/16/05.

Claims 1 and 16 are objected to because of the following informalities: it is suggested that all of the means plus function recitations be amendment into proper means plus function form, i.e. --means...for--. By adding the term --for--any future confusion as to if 112 6<sup>th</sup> applies will be eliminated. It is noted that even if applicant does not amend the claims to include the word --for--, these limitations will still be interpreted as means plus function recitations.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3763

The rejection of claims 1 and 16 under 35 U.S.C 112, sixth paragraph has been withdrawn in light of the response filed 5/16/05. Currently all means recitations (even if not followed by “for”) are being considered in means plus function interpretation since applicant positively invoked 112 6<sup>th</sup> paragraph in the response filed 5/16/05.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 11, 13-14, 16 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sealfon (USPN 5,261,882).

Regarding claims 1, 2, 16 and 19, Sealfon discloses a device (10) for the controlled delivery of an injectable liquid (36) from a liquid container (18) sealed at a rear end by a piston (26) which can slid axially in the container to deliver the liquid from an outlet (156) at a front end of the container. See figure 8. The device also includes a flexible force transferring means (interconnected spheres 80) which is axially deviated behind the container (18) away from a generally central longitudinal axis of the container. See figure 8. A drive mechanism (68) is adjacently coupled (via screw 90) to the flexible force transferring means (80) and a restoring means spiral spring to axially advance the piston (26) for delivering the liquid (18). The

Art Unit: 3763

restoring means spiral spring (helical coil 28) permanently applies a restoring force (see 3:63 and 4:25-33 for constant pulling force) to the drive mechanism (via the spring's connection with the drive mechanism through interconnected spheres 80, see figure 8) and resets it (that is the spring returns to its resting unenergized position) from a start position to an end position (see 4:51-59), thereby delivering liquid from the container.

Regarding claim 3, the drive mechanism includes a drive wheel and the flexible force transferring means is attached to a lateral facing area of the drive wheel. See figure 2 and 8.

Regarding claims 4-6 and 16, an adjustable locking means includes a rocking lever (136) having a blocking projection (96, see figure 10) at its front end and the blocking projection is formed to correspond to and cooperate with a toothed area (98) for providing controlled locking against angular adjustment of the drive wheel. See 4:48-50. The lever (134) is moveable to a releasing position in which the drive mechanism is released by advancing an operating button (100) and can be reset into a locking position in which the drive mechanism is locked by a second restoring means (not shown). See 4:50-59 and 6:1-4.

Regarding claim 7, figure 8 shows the attachment position (90) of the flexible force transferring means to the drive mechanism is substantially diametrically opposite the rear end of the liquid container (on the other side of the circular drive mechanism 68).

Regarding claims 13-14, a guide is formed by the concave portion (see figure 2) of the drive mechanism (68), the inner walls of both half casings (42,44) and a stay (76) that projects perpendicularly from the bottom casing (44) that prevents lateral bending of the transferring means because of its interconnected arrangement with the means (see 3:66-68). See figure 2.

Art Unit: 3763

Regarding claim 11, the drive mechanism (68) is configured to emit a number of audible clicks corresponding to the dosage delivered in that the prior art has the same structure as the instant invention and therefore meets the claim limitations even though the prior art does not specifically recite that clicks are produced. Specifically, the instant invention clicks are generated by the toothed area on the drive wheel contacting the blocking projection. The prior art drive wheel (68) has a toothed area (98) and contacts a blocking projection (96). The prior art structure and the fact that the elements engage one another in the way the claimed invention does, makes the prior art “configured to emit a number of clicks” even if the prior art does not specifically recite this feature.

Regarding claim 20, the restoring means (28) has a radially outer end (outer surface of 28, see figure 2) that is coupled (via screw 90) to an inner surface (concave surface) of the drive mechanism.

Additionally, Sealfon shows the device in figure 1 attached at the front end to medical tubing that has a needle for well understood intravenous service. See Figure 1 and 2:63-65.

### ***Claim Rejections - 35 USC § 103***

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Updike et al (USPN 4,568,335). Sealfon meets the claim limitations as described above but fails to include indicating the amount delivered by audible clicks.

Updike discloses a device for the controlled infusion of medications that includes a syringe with a piston. The device also includes the teaching of including audible clicks to

Art Unit: 3763

indicate the delivery of a given volume of fluid. This feature enables the use of the device without direct viewing. See 3:47-53.

At the time of the invention, it would have been obvious to include the teaching of the audible click feature as taught by Updike into the invention of Sealfon. Both devices are for administration of medicaments into a patient; therefore, a combination is proper. Additionally, one skilled in the art would recognize the advantage of the teaching of audible clicks by Updike (see Updike 3:47-53) and incorporate the feature into the invention of Sealfon in order to enhance the usability of the device for the visually impaired.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Douglas et al (USPN 6,482,186).

Sealfon meets the claim limitations as described above but fails to include the flexible force transferring means being a coil spring which is block-coiled in a region in which the coil spring is coupled to the drive mechanism.

Douglas discloses a medication delivery device that includes a flexible force transferring means that includes a cylindrical coil spring (3000) which is block-coiled (no reference number but coils are bunched together at the attachment point) at an end region for attachment to a plunger (60). See figure 2.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to use a cylindrical coil spring (as taught by Douglas) with a block-coiled region for attachment to the drive mechanism as a substitution for the flexible force transferring means of Sealfon. Both devices are analogous in the art of drug injectors and both teach mechanisms for a longitudinally diverted plunger. Additionally, applicant has failed to disclose that the flexible

Art Unit: 3763

force transferring means being a coil spring with a block-coil serves any advantage, particular purpose, or solves a stated problem. Furthermore, one would have expected Sealfon's transferring means and the claimed cylindrical coil with the block-coiled region (see Douglas) to perform equally well because both structures would perform the same function, i.e. angular displacement from the longitudinal axis of the piston to reduce the overall profile of the device since both structures are designed to bend.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sealfon in view of Utterberg et al (USPN 5,112,311). Sealfon meets the claim limitations as described above, including a teaching of a injection needle at the front end of the container, but fails to include specifically include a 30 or 31 gauge injection needle.

Utterberg discloses a winged IV infusion assembly that includes the general background teaching of a standard 30-gauge needle for administering IV fluids. See background 1:19-29.

At the time of the invention, it would have been obvious to one skilled in the art to incorporate the teaching of the 30-gauge needle by Utterberg into the invention of Sealfon. Sealfon discloses the use of a needle (see above) and Utterberg provides a specific needle for that purpose, i.e. intravenous fluid administration. Since both devices relate to intravenous fluid administration, a combination is proper. Additionally, 30-gauge needles are well known in the art and as evidenced by Utterberg are a standard gauge for IV injection. The motivation for the incorporation is found in both references in that Sealfon discloses a needle and Utterberg provides a specific needle for achieving the structure and function, i.e. iv fluid administration.



*Response to Arguments*

Applicant's arguments filed 5/16/05 have been fully considered but they are not persuasive.

Applicant argues that the spindle (68) is not coupled to the spheres (80/82). The spindle and spheres are coupled via screw 90. See above and figure 2.

Applicant further states that the drive mechanism (spindle 68) is not "to advance a piston". A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In this case, the drive mechanism is capable of advancing the piston (spheres 80/82) since the drive mechanism (68) is both coupled to the piston (80/82) via the screw 90 and also capable of rotating and thereby rotating the piston. If the drive mechanism is rotated counter-clockwise, i.e. by another mechanism or by hand, that rotation will directly result in the advancing of the piston. Hence, the spindle (68) is a drive mechanism and capable of advancing the piston.

Regarding claim 16 and the application of a restoring force of a spring to the drive wheel, the same argument as above to the drive mechanism capable of advancing the piston applies here.

Regarding new claim 19-20 see rejection above.

Art Unit: 3763

Regarding applicants comments to the 103 rejections, applicant does not argue the merits of the respective combinations, rather that the primary reference (Sealfon) does not teach elements of the claims. Therefore, it is assumed that the respective combination of the references is not contested.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
July 15, 2005



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700